

Overview Of FDA's Postmarket Program For Medical Devices

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In 2005 FDA's Center for Devices and Radiological Health (CDRH) issued an assessment of the tools used for monitoring the safety of medical devices after FDA approves the products (postmarket). This was largely a result of several highly visible medical device recalls, thereby subjecting FDA to significant scrutiny and public expectations for an assessment of the current adverse event system. This assessment resulted in formation (January 2006) of a Postmarket Transformation Leadership Team to develop an action plan for change.

Subsequently, in November 2006, the Team issued a report¹ of the CDRH plans for improving the postmarket system. The Report, briefly summarized in this article, provides a detailed summary of four major action areas with specific recommendations per area.

The major action areas of the Report are:

1. Create a Culture of Collaboration
2. Develop World Class Information Systems
3. Enhance Risk-Benefit Communication Efforts
4. Focus Enforcement Strategies

1. Create a Culture of Collaboration

CDRH's goal to create a culture of collaboration is to operate CDRH as a coordinated whole, rather than a collection of pieces (independent areas/offices of CDRH).

Understanding of and commitment to a common mission is critical to the success of any organization. To institutionalize a collaborative culture, CDRH should identify the characteristics of the culture it seeks, and should ensure that staff understand the processes and have the skills (e.g., conflict resolution, team building, communication abilities) to realize transformation.

2. Develop World Class Information System

Through the use of a world class information system CDRH's goal is to collect data on postmarket device performance from both regulatory and non-regulatory sources, and efficiently analyze that data to detect signals of adverse device performance. Currently the main source of information on postmarket device performance is Medical Device Reporting (MDR). The critical challenge is to improve MDR, complement it with other data collection mechanisms, and make the data more widely available across CDRH.

3. Enhance Risk-Benefit Communication Efforts

The goal of CDRH relative to enhancing risk-benefit communications is to maximize the ability to communicate information in a clear and timely way to practitioners (clinicians, physicians), patients and consumers. At least two types of messages must be accommodated; communication to the public of non-emergency public health messages and communication of time-critical information, (e.g., a Class I recall). These tasks involve examining interactions with health care practitioners and institutions, and determining how to create and use routine communication channels with these groups.

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4. Focus Enforcement Strategies

CDRH's goal for focused enforcement strategies is to improve prioritization, coordination, consistency, quality and timeliness of inspections, reporting and enforcement decisions. Relief in the form of increased appropriations or the introduction of user fees for inspections is not likely. Rather, success is more likely to be found in focused enforcement efforts, (e.g., prioritizing and targeting efforts), building improved data systems and leveraging the information obtained in audits conducted by other global regulatory bodies.

FDA'S IMMEDIATE ACTIONS:

- Creating a matrix of collaborative product groups to complement the largely functional organization of CDRH
- Developing metrics and methods for tracking the handling of postmarket issues
- Proposing mandatory electronic MDR reporting
- Revising and updating current reporting systems and expanding the premarket data-warehousing project to include postmarket needs
- Pursuing the development of unique identifiers for medical devices
- Increasing the quality and quantity of CDRH interactions with other FDA enforcement groups
- Developing and implementing a risk-communication strategy
- Designing a pilot project to test the usefulness of quantitative decision-making methods for medical device regulation across the total product life cycle

CDRH hopes to have a more defined implementation plan in 2007.

¹The plan, **Report of the Postmarket Transformation Leadership Team: Strengthening FDA's Postmarket Program for Medical Devices**, November 2006, is located at <http://www.fda.gov/cdrh/postmarket/mdpi.html>.

The following related documents can also be found at this web address:

- *Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program*, Jan 06
- *Synopsis and Recommendations*, Jan 06
- *Ensuring the Safety of Marketed Medical Devices*, Jan 06

Jennifer Marrone, MBA (jmarrone@rcri-inc.com) is a founder of RCRI, Inc. and a Senior Principal Advisor in worldwide regulatory and clinical affairs. In her 25 years in the medical device industry, she has prepared regulatory submissions, negotiated with governmental authorities, and interacted with clinicians. Her experience in executive management, staff development and management, along with her hands-on expertise in regulatory, quality and clinical affairs, both US and internationally, enable her to provide innovative service to the medical device industry. Jennifer regularly presents on regulatory affairs, clinical study and quality/compliance topics at industry and trade association meetings.

Did you know...?

Did you know a comprehensive clinical database that has been validated vigorously is an important tool for monitoring your study and safeguarding the integrity of your results? Developing a robust clinical database that meets your specific needs does not have to be a costly and frustrating experience.

RCRI's goals are to develop databases and reporting tools that meet your specific needs, stand up to the rigors of your clinical trial, and meet regulatory standards in a timely and cost-effective manner.

RCRI specializes in developing customized databases that:

- Meet 21 CFR Part 11 requirements
- Allow for data entry via RCRI's expert staff or via remote data entry
- Provide efficient data retrieval for report generation or sponsor access
- Provide seamless Integration with SAS[®] analysis tool
- Are completely customizable to your study needs

With RCRI, you can be assured that your database will be developed efficiently, and that it will operate effectively with your clinical trial.

To learn more, contact Juli Denny, Director of Business Development, at jdenny@rcri-inc.com



RCRI Dedication to Quality Evident During Annual ISO 9001 Surveillance Audit

The Regulatory & Clinical Research Institute is very pleased to announce that our BSI auditor found no major or minor nonconformities in an ISO 9001:2000 surveillance audit completed in August 2006.

The ISO 9001:2000 standard is an internationally recognized quality management system standard that focuses on operational efficiency and process control. ISO enables companies to monitor and correct their business practices, thereby increasing customer satisfaction and in many cases reducing time and cost of product delivery. The objective of the required audit was to determine the extent of ongoing conformity of RCRI's management system with audit criteria of the ISO 9001:2000 standard, evaluate our ability to meet internal and external objectives, and identify areas of potential improvement of the management system.

Our outstanding performance illustrates that RCRI personnel are diligently working to thoroughly understand customer needs, and then apply the appropriate resources to meet the customer's specifications and exceed their expectations. Various internal processes are utilized by RCRI to link and control activities and resources which must be managed to achieve the desired outputs. The Quality Management Principles in ISO 9001:2000 (customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making) are used by RCRI to improve and strengthen our quality management system.



RCRI Continues to Improve Through Your Feedback

RCRI's Customer Satisfaction Survey program, while illustrating our dedication to ISO 9001:2000 principles, is also a forum for your feedback. Customers, like yourself, are sent satisfaction surveys when key project milestones are reached and upon project completion. Every response is charted and reviewed in keeping with our ongoing commitment to continual process improvement. Your feedback is essential in our ability to assess and improve our customer service.

Here are just a handful of the comments we received from you in 2006:

- "RCRI is a valuable resource that I use for special projects. They have done a terrific job supporting my needs..."
- "It was a real pleasure working with everyone at RCRI. We're keeping your number at the top of our speed dial!"
- "I just wanted to take the opportunity to express our appreciation to the quality of the resources, their clear understanding of the work to be done, and their high level of commitment to our project."
- "Our experience with RCRI, and (one consultant) in particular was fantastic. (She) came to the project with an understanding of our industry, learned and understood our requirements completely, and provided very high quality results on time and within budget. We are looking forward to our next engagement with RCRI."
- "We were very pleased with the direction and professional expertise that (our consultant) brought to this project. She kept us on track and always got her part done on time. Working with her was a pleasure. We appreciated RCRI's help with this project. We felt that you pulled together as a team to meet our needs. Thank you."

We are pleased to say that **97% of you answered YES** when asked "Would you give a favorable recommendation to others in/outside of your organization?"

Thank you to all of you for your comments and suggestions. We are proud of our consultants and the outstanding services they provide. With your feedback we continue to refine our customer service, so we can offer world-class consulting services that are in line with your expectations.

New Staff Appointments at RCRI

RCRI is delighted to announce the addition of several new staff members.



Dale Klous, BA, RRT
Director of Clinical Operations

Dale has over 25 years of clinical and research industry experience. He has held a number of senior level positions with medical device companies, contract research organizations, and the University of Minnesota. Dale brings a wealth of knowledge to RCRI. Throughout his career, he has managed over 60 medical device and pharmaceutical clinical trials, covering a broad spectrum of therapeutic areas. In addition to clinical operations expertise, Dale has a solid background in product development and strategic planning. Our clients benefit from his broad background and the depth of his expertise.



Russell Olson
Vice President Regulatory Affairs & Quality Systems

Russell Olson brings over 25 years of regulatory and quality system experience to RCRI. He has participated in strategic planning for corporate and product development for venture funded development as well as major device companies. Russell has extensive experience with US and international regulatory agencies for product approval, compliance activities, as well as quality system certification. He has participated in corporate funding events and can add the value of the regulatory and quality system functions to help in the valuation of new companies. Russell leads the regulatory and quality functions while participating as a Senior Principal Advisor to further support client needs.



Natasha Rodich, MA
Director of Human Resources

Natasha brings over fourteen years of outstanding human resources experience to RCRI. She previously held leadership positions with SYSCO and prior to that was involved with Sales and Marketing for Paddock Laboratories, Inc. Her overall knowledge of Human Resources is complemented by her Masters degree in Industrial Relations. Rodich stated, "I am enthusiastic about the opportunity to be working with an organization that has an incredible talent pool and further encourages this talent acquisition through their focus on benefits and flexibility."

Nancy Blyler, Senior Clinical Research Associate

Nancy's background includes experience in clinical research, quality assurance, and regulatory compliance. Her expertise is highlighted by management of clinical research studies involving the collection and transplantation of umbilical cord stem cells. She has designed and implemented quality systems, managed both internal and external audits, and directed numerous quality improvement projects at GMP-compliant facilities. Nancy holds a BA in Biology and is certified as a Medical Technologist with a specialist certification in blood bank technology.

Melissa Steinwedel

Clinical Proposal Coordinator & Clinical Research Associate
Melissa graduated from Purdue University with a BA in Public Relations and a minor in English. Melissa has 2 years of clinical industry experience on the sponsor side, specializing in oncology. She recently completed the CRA/CRC Program Series offered by Barnett International. Prior to working in the pharmaceutical industry, Melissa worked for the Secretary of Health in Oklahoma with a study impacting the under-treated citizens of Oklahoma battling mental illness, substance abuse, and domestic violence.

Adam Burnham, Information Systems Analyst

Adam holds a degree in Electrical Engineering from North Dakota State University. His engineering experience extends to General Motors, Goodrich Sensor Systems, and Digi. He transitioned from hardware design into information technology with Target Corporation.

Jason Rogowski, Biostatistician

Jason has a BA in Mathematics from Gustavus Adolphus College. While obtaining an MPH in Epidemiology from the University of Minnesota, Jason gained valuable experience as a research assistant for two genetic epidemiology studies and the Minnesota Department of Health. Jason also interned at RCRI. We are thrilled to permanently add him to our staff.

Sujatha Sitaraman, PhD

Assistant Clinical Research Associate
Sujatha, a native of India, completed post doctoral research at the University of Michigan in Cell Biology while concurrently seeking certification as a clinical coordinator at Eastern Michigan University. As an intern she was introduced to the world of clinical studies where she applied her basic research skills to clinical research. Sujatha also holds an undergraduate degree in Biochemistry.

RCRI's Experts Share Their Experience

Learn from RCRI's experts as they share their knowledge and experience during the following presentations.

LifeScience Alley Clinical Research 101

February 21, Minneapolis, MN

"Adverse Events and Protocol Deviations"

Mary Kay Sobcinski, RN, *Principal Advisor*

University of Minnesota

March 2, Minneapolis, MN

"Clinical Research Methods"

Steve Norsted, PhD, MPH, *President & CEO*

University of St. Thomas

April 12, Minneapolis, MN

"Medical Device Clinical Trials"

Steve Norsted, PhD, MPH, *President & CEO*

Association of Medical Diagnostic Manufacturers Annual Meeting

April 19-20, Bethesda, MD

"Working with a CRO"

Marilyn Waxberg, MBA, *Principal Advisor*

ACRP Global Conference & Exhibition

April 20-24, Seattle, WA

"E-Labeling and Software Validation"

Russell Olson, *VP Regulatory Affairs & Quality Systems*

Pharma MedDevice 2007

April 24-26, New York, NY

"The Marketing Application Process for Combination Products"

Marilyn Waxberg, MBA, *Principal Advisor*

University of Minnesota Biomedical Engineering Institute Short Course, Preservation of Cells, Tissues, and Gametes

May 16-18, Minneapolis, MN

"Regulatory Issues and Challenges"

Marilyn Waxberg, MBA, *Principal Advisor*

16th Annual SoCRA Conference

September 27-30, Denver, CO

"Monitoring and Trial Conduct: Perspectives from a Coordinator, an FDA Reviewer, and a Statistician"

Chris Lyle, *Director of Biostatistics & Health Economics*

UPCOMING EVENTS

Visit us at the following conferences to discover how RCRI can assist you with your next project.

- **Invest Northwest Investor & CEO Forum**
March 20-21, 2007
Seattle, WA
- **RAPS Horizons Conference & Exhibition**
March 28-30, 2007
San Francisco, CA
- **ACRP Global Conference & Exhibition**
April 20-24, 2007
Seattle, WA
- **RAPS Annual Conference & Exhibition**
September 23-26, 2007
Boston, MA
- **6th Annual LifeScience Alley Conference & Expo**
December 6, 2006
St. Paul, MN

KNOWLEDGE, INTEGRITY, & INGENUITY

Our mission is to serve our clients with knowledge, integrity, and ingenuity. At RCRI, we are proud of our successful record in providing integrated CRO services to the medical device, IVD, biologics, and combination product industries.

Since our inception in 1999, RCRI has helped more than 220 companies worldwide – development stage start-ups as well as the largest Fortune 500 companies – translate their product plans into successful revenue generating businesses.

Whether it is a single task or a complex multi-faceted project, you can count on the experienced professionals at RCRI.

Contact us today to discuss how we can assist you with your next project.

**Visit us online and subscribe to RCRI's
free newsletter at www.rcri-inc.com**

FDA Fiscal Year 2007 Device User Fees

The following table denotes FDA Fiscal Year 2007 Device User Fee Rates.

Fees are effective for any application or supplement that is received on or after October 1, 2006 through September 30, 2007.

Application Fee Type	2007		2006	
	Standard Fee	Small Business Fee*	Standard Fee	Small Business Fee
Premarket Application (PMA, PDP, BLA, PMR) **	\$281,600	\$107,008	\$259,600	\$98,648
Premarket Report	\$281,600	\$107,008	\$259,600	\$98,648
Panel Track Supplement	\$281,600	\$107,008	\$259,600	\$98,648
Efficacy Supplement	\$281,600	\$107,008	\$259,600	\$98,648
180-Day Supplement	\$60,544	\$23,007	\$55,814	\$21,209
Real-time Supplement	\$20,275	\$7,705	\$18,691	\$7,103
Premarket Notification [510(k)]	\$4,158	\$3,326	\$3,833	\$3,066

*Firms with annual gross sales or receipts of \$100 million or less, including affiliates, partners, and parent firms, may qualify for lower rates for all applications that are subject to a fee.

**Firms with annual gross sales or receipts of \$30 million or less, including affiliates, partners, and parent firms, may qualify for a fee waiver for their first PMA.

For more information, visit www.fda.gov/cdrh/mdufma/index.html or contact Juli Denny, Director of Business Development, at jdenny@rcri-inc.com.



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